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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,033	06/27/2001	Genichi Kakefuda		3401

7590 02/07/2005  
Sutherland Asbill & Brennan LLP  
999 Peachtree Street N.E.  
Atlanta, GA 30309-3996

EXAMINER

SAIDHA, TEKCHAND

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/893,033

**Applicant(s)**

KAKEFUDA ET AL.

**Examiner**

Tekchand Saidha

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38,39,41-48,52,53,55-62 and 84-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-39, 42-48, 52-53, 56-62, 84 & 87-88 is/are rejected.
- 7) ☒ Claim(s) 41,55,85 and 86 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **Final Rejection**

1. Applicants' amendment filed December 22, 2004, in response to Office Action mailed August 18, 2004, is acknowledged. Claims 11-37, 40, 49-51, 54, 63-83 have been cancelled.

2. Claims 38-39, 41-48, 52-53, 55-62 and 84-88 are pending and under consideration in this Office Action.

### **3. Abstract**

\*This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). **An abstract on a separate sheet is required.**

\*The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 150 words [in length since the space provided for the abstract on the computer tape by the printer is limited]. The form and legal phraseology often used in patent claims, such as "means" and "said", should be avoided in the abstract. The abstract should sufficiently describe the disclosure to assist readers in deciding whether there is a need for consulting the full patent text for details. MPEP 608.01(b).

The newly submitted abstract is not on a separate sheet.

### **Specification**

Applicants amended specification by deleting hyperlink (see amendment to specification, page 2, lines 1-3). In the process the sentence has been left incomplete. Deleting the entire sentence or amending the sentence to a complete one is required.

4. Claims 38-39, 41-48, 52-53, 55-62 and 84-88 are pending and under consideration in this examination.

5. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.

6. Applicant's arguments filed as per the amendment cited above have been fully considered but they are not deemed to be persuasive. The reasons are discussed following the rejection(s).

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7. **New Matter added to claims only** – [New Matter rejection]

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-39, 42-48, 52-53, 56-62, 84 & 87-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), **at the time the application was filed**, had possession of the claimed invention. Applicant's addition [new matter] of 'at least 90% sequence identity..' in claims 38-39, 42-48, 52-53, 56-62, 84 & 87-88, either direct or in a dependent manner, is not supported by the original disclosure. Applicants are required to cancel the new matter in reply to this office action.

8. **Claim Rejections - 35 USC §112** (first paragraph)

Claims 38-39, 42-48, 52-53, 56-62, 84 & 87-88 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for *Synechocystis* PCC 6803 polynucleotides of SEQ ID NO: 6 and 17 encoding AHAS large and small subunits respectively, does not reasonably provide enablement for any polynucleotide at least 90% identical to the polynucleotide sequence of SEQ ID Nos. 6 or 17, encoding AHAS large and small subunits from any cyanobacterium [or *Synechocystis*] or a method based thereon (claims 38-39, 42-48, 52-53, 56-62, 84 & 87-88), or wherein the AHAS large/small subunit gene confers resistance to a herbicide or a vector comprising such a

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polynucleotide or a nuclear genome (complete set of genetic material present in the nucleus) comprising the vector or a plastome (the genetic complement of a plastid) comprising the vector or a transgenic plant produced from the transformation of the replicable expression vector or its progeny. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988))[ *Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. & Int. 1986)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim. The factors most relevant to this rejection are [the scope of the claims, unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary].

The specification, however, only discloses the full length sequence of a polynucleotide of SEQ ID NO: 6 & 17 encoding AHAS large and small subunits respectively. There is no disclosure or description of other polynucleotide(s) encoding the AHAS large and small subunits from other sources, or even from *Synechocystis*, and its further transformation into a replicable vector, nuclear genome, plastome or a transgenic plant. Despite knowledge in the art for the isolation of homologous genes from a variety of sources, given the structure and function of a single gene (or polynucleotides), the claims encompass enormous numbers of polynucleotides with no known structural similarity to aid one skilled in the art selectively isolate other AHAS encoding polynucleotide(s) from any cyanobacterium or *Synechocystis*.

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The specification does not support the broad scope of the claims which encompass any polynucleotide encoding AHAS large and small subunits from any cyanobacterium, because the specification does **not** establish: (A) regions of the protein structure which may be conserved without effecting AHAS activity; (B) the general occurrence of AHAS; (C) a rational and predictable scheme for isolating any AHAS from any cyanobacterium with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Without such guidance, the experimentation left to those skilled in the art is undue.

Applicants' arguments:

Applicants argue that the claims as amended are enabled by the specification. Applicants further state, citing specific pages and lines in the instant specification, teachings pertaining to the construction of nuclear expression vector comprising the claimed polynucleotides and method of transforming a plant with either the nuclear or plastid expression vector; and that the specification also teaches that the disclosed sequences confer upon a transgenic plant increased resistance to imidazolinone and sulfonylurea.

In response Applicants are reminded that 'at least 90% sequence identity with respect to the claimed sequences' is without basis in the specification. The rejection is therefore maintained.

9. **Priority:** In evaluating the prior art, Applicants were deemed to be entitled to an **effective filing date of 6.27.2001**, the filing date of this application [09/893,033]. The priority document was examined from the prior application, serial number, 60/214,705, and was determined to be lacking an enabling disclosure with respect to the claimed invention. The instant application is therefore not entitled to an effective filing date earlier than 6.27.2000.

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Applicants' provisional application 60/214,705, does not contain any sequence listing, and SEQ ID Nos. 6 & 17 are not disclosed in the priority document. Further, Figures 11-15, describing the AHAS gene constructs, are present in the instant application, but are lacking in the provisional application.

Applicants Arguments:

Applicants argue that even though the sequences were **not** specifically disclosed in the provisional application, Applicants were clearly in possession of the AHAS large and small subunits from *Synenchocystis* PCC 6803 and provided sufficient description within the specification to enable one of ordinary skill in the art to practice the invention as claimed.

Applicants' arguments were considered and not found to be persuasive, because this is not an issue of enablement, it is an issue of what is described or disclosed in the provisional application for which the priority is being sought. Since there is basis for the actual sequences in the provisional application Applicants are deemed to be entitled to an **effective filing date of 6.27.2001**, the filing date of this application [09/893,033].

10. Claims 41, 55 & 85-86 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. During a telephone interview with the Applicants representative, William L. Warren, on January 21, allowable subject matters were discussed and Applicants were invited to amend the claims by deleting the % identity language, to place them in condition for allowance. However, the discussion did not result in an agreement being reached hence this Office Action.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

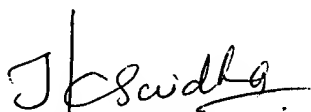
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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February 4, 2005